

§ 71.129 Inspection, test, and operating status.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

(b) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

§ 71.131 Nonconforming materials, parts, or components.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

§ 71.133 Corrective action.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

§ 71.135 Quality assurance records.

The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by § 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a CoC shall retain these records for 3 years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for 3 years after it is superseded.

§ 71.137 Audits.

The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

APPENDIX A TO PART 71—
DETERMINATION OF A₁ AND A₂

I. Values of A₁ and A₂ for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The Terabecquerel values are the regulatory